

The First Civil Rights Act of the 21st Century: Genetic Information Nondiscrimination Act of 2008

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Abstract: Since the Human Genome Project began in the 1990s as an effort to map out all amino acid sequences of the human genome, concern over the misuse of genetic information paralleled the excitement of unlocking the human genetic code. A patchwork of incomplete and unclear laws derailed efforts intended to prevent genetic discrimination and to protect the privacy of genetic information. Embodied in state and federal statutes, such as the Health Insurance Portability and Accountability Act, Americans with Disabilities Act, and Civil Rights Act,¹ these genetic privacy laws have been inconsistently enforced. In an attempt to unify the regulation of genetic discrimination, the federal government sought to create a comprehensive federal statute to prohibit discrimination based on genetic information. Finally, on May 21, 2008, President Bush signed into law the Genetic Information Nondiscrimination Act of 2008 ("GINA"),² regarded as the first civil rights act of

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¹ Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996); Americans with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327 (1990); Civil Rights Act of 1964, Pub. L. No. 88-352, 78 Stat. 241 (1964).

² H.R. 493, 110th Cong. (2008).

the twenty-first century.³ GINA addressed genetic discrimination and the privacy of genetic information in two settings: health insurance and employment.

This note begins with an introduction to the benefits of genetic testing, potential instances of genetic discrimination in health insurance and employment settings, and the negative impact of genetic discrimination. Second, this note explores the scope of federal statutes before the enactment of GINA and state genetic nondiscrimination statutes. Finally, this note examines the development and scope of the newly enacted GINA and its implication for the future protection of genetic information.

³ Press Release, Sen. Ted Kennedy, Kennedy in Support of Genetic Info. Nondiscrimination Bill (Apr. 24, 2008), *available at* http://kenedy.senate.gov/newsroom/press_release.cfm?id=4fcf8e86-4706-4e74-b451-36253c5a425d.

I. INTRODUCTION

In the spring of 2003, the Human Genome Project was completed.⁴ After thirteen years of collaborative international efforts among research institutions, the finished sequence of the human genome, which consisted of overlapping fragments covering 99% of the coding regions with an accuracy of 99.999%, was deposited into a public database for genetic testing and research.⁵ The completion of the Human Genome Project opened a new door for the field of genetics, allowing scientists and researchers to identify genetic markers for potentially thousands of diseases and health conditions—including Alzheimer's disease, Huntington's disease, and cystic fibrosis.⁶

The ability to discover genetic characteristics provides a valuable way to identify genes linked with certain diseases and for the potential to treat and cure such diseases. Nonetheless, this new surge in genetic information raises concerns about genetic privacy and possible discrimination in health insurance and employment. Specifically, the presence of a certain gene sequence in an individual may indicate predisposition to a disease, but does not assure that the disease will manifest in that individual. An employer or a health insurance company may use this information about genetic predispositions to

⁴ Human Genome Project Info., History of Human Genome Project [hereinafter History of Human Genome Project], http://www.ornl.gov/sci/techresources/Human_Genome/project/hgp.shtml (last visited Feb. 19, 2009).

⁵ Press Release, Nat'l Inst. of Health, Int'l Human Genome Sequencing Consortium Describes Finished Human Genome Sequence (Oct. 20, 2004), *available at* <http://www.genome.gov/12513430>.

⁶ *The Potential for Discrimination in Health Insurance Based on Predictive Genetic Tests: Hearing Before the Subcomm. on Commerce, Trade and Consumer Protection of the H. Comm. on Energy and Commerce*, 107th Cong. (2001) (testimony of Mary E. Davidson, Executive Director, Genetic Alliance), *available at* http://digitalcommons.law.umaryland.edu/cgi/viewcontent.cgi?article=1016&context=con_g_test; Press Release, Nat'l Inst. of Health, Consensus Development Conference on Genetic Testing for Cystic Fibrosis (Apr. 9, 1997), *available at* <http://consensus.nih.gov/1997/1997GeneticTestCysticFibrosis106html.htm>; Huntington's Disease Society of America, Inc., Guidelines for Genetic Testing for Huntington's Disease (revised 1994), <http://dwb4.unl.edu/Chem/CHEM869N/CHEM869NLinks/www.hdfoundation.org/testread/hdsatest.htm>; Kingdom Hosp. Consulting Clinics, *Discovery Could ID Diabetes-Risk Kids*, July 12, 2004, <http://www.khccgroup.com/item.php?IID=16>.

discriminate against an individual when making hiring decisions or, in the case of an insurance company, when writing insurance policies. Although there are state and federal laws addressing genetic discrimination, they are incomplete in both “the scope and depth of [their] protections.”⁷ Since the completion of the Human Genome Project, many attempts have been made to create more comprehensive federal genetic discrimination legislation.⁸ Finally, in May 2008, President Bush signed the first comprehensive Genetic Information Nondiscrimination Act (“GINA”) into law.⁹

This note will first address the social policy reasons for prohibiting employers and health insurance companies from using genetic information. Next, this note discusses state and federal law prior to the enactment of GINA, and it will analyze these laws for weaknesses. Finally, this note will closely examine GINA and its consequences in relation to genetic privacy and discrimination.

II. GENETIC INFORMATION AND ITS IMPACT ON SOCIETY

A. HUMAN GENOME PROJECT

In 1990, the United States Department of Energy and the National Institutes of Health initiated a three billion dollar¹⁰ research project to determine the sequence of amino acid base pairs that make up DNA, and to identify the function and physical locations of all genes in the human genome.¹¹ After thirteen years, the Human Genome Project ended in success with a completed human genome sequence being

⁷ ROBERT B. LANMAN, AN ANALYSIS OF THE ADEQUACY OF CURRENT LAW IN PROTECTING AGAINST GENETIC DISCRIMINATION IN HEALTH INSURANCE AND EMPLOYMENT 4 (2005), oba.od.nih.gov/oba/sacghs/reports/legal_analysis_May2005.pdf.

⁸ Genetic Info. Nondiscrimination Act of 2003, S. 1053, 108th Cong. (2003); Genetic Info. Nondiscrimination Act of 2005, H.R. 1227, 109th Cong. (2005).

⁹ Genetic Info. Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881, available at <http://www.govtrack.us/congress/billtext.xpd?bill=h110-493&show-changes=0&page-command=print>.

¹⁰ Human Genome Project Info., Human Genome Project Budget, http://www.ornl.gov/sci/techresources/Human_Genome/project/budget.shtml (last visited Feb. 19, 2009).

¹¹ History of the Human Genome Project, *supra* note 4.

deposited into a public database.¹² The final product “covers more than ninety-nine percent of the euchromatic (gene-containing) portion of the human genome and was sequenced to an accuracy of 99.999 percent, which translates to an error rate of only one base pair per 100,000 base pairs— ten times more accurate than the original goal.”¹³

Because we now have a better understanding of the human genome, there are more than 1000 genetic tests available to identify a person’s predisposition to specific conditions or diseases, such as sickle cell anemia, degenerative neurological diseases (e.g., Huntington’s disease), and certain forms of cancer.¹⁴ Genetic testing can assist with diagnosing an individual’s genetic condition, determining the best treatment method based on an individual’s genetic make-up, predicting risk of future disease, informing “reproductive decision making,” and choosing the correct medication.¹⁵ Knowledge about an individual’s genetic make-up can help that person take proactive steps to protect his health and to lower his health care costs, and even the costs to society as a whole.

However, the amount of genetic information that may be subject to use for non-medical purposes has increased greatly because genetic testing has become widely available. In congressional testimony, Dr. Francis Collins, the Director of the National Human Genome Research Institute, expressed concerns about misuse of genetic information:

[W]hile genetic information and genetic technology hold great promise for improving human health, they can also be used in ways that are fundamentally unjust. Genetic information can be used as the basis for

¹² Press Release, Nat’l Inst. of Health, International Human Genome Sequencing Consortium Describes Finished Human Genome Sequence (Oct. 20, 2004), *available at* <http://www.genome.gov/12513430>.

¹³ *Id.*

¹⁴ Human Genome Project Info., Gene Testing, http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetest.shtml (last visited Feb. 19, 2009).

¹⁵ Press Release, Genetics & Pub. Policy Ctr., U.S. Public Opinion on Uses of Genetic Information and Genetic Discrimination (Apr. 24, 2007) (on file with author); Genetic Testing, Medline Plus, <http://www.nlm.nih.gov/medlineplus/genetictesting.html> (last visited Feb. 19, 2009).

insidious discrimination . . . [t]he misuse of genetic information has the potential to be a very serious problem, both in terms of people's access to employment and health insurance and the continued ability to undertake important genetic research.¹⁶

Specifically, two significant concerns arise: (1) whether an insurance company can use genetic information to deny coverage or to set rates for insurance policies, and (2) whether an employer can use genetic information as a factor in hiring or firing a potential employee.

B. GENETIC INFORMATION AND HEALTH INSURANCE

Because of the high cost of medical care in the United States, health insurance is a necessity. In the current American health care system, each individual's risk of disease affects his or her cost and access to health care coverage. Genetic discrimination in health insurance can occur in two ways: (1) the health insurer may use genetic information to refuse to insure someone or (2) the health insurer may use genetic information to refuse to provide coverage for a particular treatment. The use of genetic information and the availability of health coverage are often inversely related, such that when more genetic information is available, "those most in need [of health care] may have the greatest difficulty finding affordable health care coverage."¹⁷

In the early 1970s, African Americans who were carriers of the gene for sickle cell anemia were either denied coverage or charged a higher rate by insurance companies.¹⁸ In a recent survey, 22% of the people with a known genetic condition in the family, "indicated that

¹⁶ *Hearing on Genetic Information in the Workplace Before the S. Comm. on Health, Education, Labor and Pensions*, 106th Cong. (2000) (testimony of Francis S. Collins, Director, Nat'l Human Genome Research Inst., Nat'l Inst. of Health) [hereinafter *Hearing on Genetic Information in the Workplace*], available at <http://www.genome.gov/10001380>.

¹⁷ NAT'L HUMAN GENOME RESEARCH INST., GENETIC INFORMATION AND HEALTH INSURANCE REPORT OF THE TASK FORCE ON GENETIC INFORMATION AND INSURANCE (May 10, 1993) [hereinafter GENETIC INFORMATION AND HEALTH INSURANCE REPORT], available at <http://www.genome.gov/10001750>.

¹⁸ Kathy L. Hudson et al., *Genetic Discrimination and Health Insurance*, 4 VHL FAMILY ALLIANCE 9, 9-10 (Mar. 1996), available at <http://www.vhl.org/newsletter/vhl1996/96aqinsu.htm>.

they had been refused health insurance coverage because of their genetic status, whether they were sick or not.”¹⁹

Although most people recognize the importance of special protection of genetic information from unauthorized disclosure, as a practical matter, it is difficult to enforce such protection. First, genetic information is not clearly distinguishable from other health information, such as medical records.²⁰ Secondly, difficulty arises in defining a medical condition as genetic or non-genetic because these conditions usually encompass both genetic and non-genetic components.²¹

Most states have enacted their own genetic nondiscrimination acts to resolve the public concern over disclosure of private, genetic information,²² but none of the state laws completely answer the guidelines set out by the U.S. Preventive Services Task Force (“Task Force”).²³ With the enactment of GINA, which will become effective in the summer of 2009, the federal government created a comprehensive plan that satisfies the concerns of the Task Force.

C. GENETIC INFORMATION AND WORKPLACE

Employers are facing increasingly tough decisions as genetic testing is becoming more prevalent. At one end, the employer may feel obligated to utilize genetic testing to ascertain employees’ predisposition to diseases to comply with the Occupational Safety and Health Administration (“OSHA”) regulations and to avoid negligence-based lawsuits for failure to provide a safe workplace. The Occupational Safety and Health Act of 1970 places a duty on employers to “furnish to each of his employees a place of employment

¹⁹ *Id.*

²⁰ GENETIC INFORMATION AND HEALTH INSURANCE REPORT, *supra* note 17.

²¹ *Id.*

²² Sonia Suter, *The Allure and Peril of Genetics Exceptionalism: Do We Need Special Genetics Legislation?*, 79 WASH. U.L.Q. 3 (2001).

²³ Ellen Wright Clayton, *Ethical, Legal, and Social Implications of Genomic Medicine*, 349 NEW ENG. J. MED. 562, 564 (2007). The U.S. Preventive Services Task Force (“USPSTF”) is “an independent panel of experts in primary care and prevention that systematically reviews the evidence of effectiveness and develops recommendations for clinical preventive services.” The USPSTF was created by the U.S. Public Health Service in 1984. U.S. Dep’t of Health & Hum. Servs., Frequently Asked Questions, http://info.ahrq.gov/cgi-bin/ahrq.cfg/php/enduser/std_alp.php (last visited Feb. 19, 2009).

which [is] free from recognized hazards that are causing or likely to cause death or serious physical harm.”²⁴ Because the aim of this legislation is to prevent workplace harm, the taking of genetic information from employees may be viewed as a requisite to providing a safe working environment by preventing employees with illnesses or diseases from entering the workplace because they could place other employees at risk.

In addition, because of the simultaneous increase in employee and retiree health care costs and the decrease in the cost of genetic testing, it is in an employer’s best interest to screen for genetic susceptibility to disease and to make employment decisions with knowledge of such data. For instance, if an employer is faced with two equally qualified applicants, but one has a high likelihood of developing a costly disease and the other has a low probability of developing an illness, the employer may look at that health risk as a factor in determining which candidate to hire.

On the other end, by testing employees, employers may be in violation of a variety of federal and state anti-discrimination statutes, such as the Americans with Disabilities Act (“ADA”) and Title VII of the Civil Rights Act. In 2001, the Burlington Northern Santa Fe Railway Company (“Burlington Northern”) agreed to stop genetic testing of its employees as part of a settlement with the U.S. Equal Employment Opportunity Commission (“EEOC”).²⁵ The EEOC brought action against Burlington Northern to stop the railroad from “requiring all union members who claim work related [sic] Carpal Tunnel Syndrome to provide blood samples for a DNA test for a condition that may predict some forms of Carpal Tunnel Syndrome.”²⁶ The railroad employees were asked for blood samples (without consent for genetic testing), and an employee who refused to provide a sample was threatened with termination.²⁷ The EEOC claimed that the test violated the ADA by subjecting the employees, without their

²⁴ Occupational Safety and Health Act of 1970, Pub. L. No. 91-596, 84 Stat. 1590 (1970).

²⁵ Sarah Schafer, *Railroad Agrees to Stop Gene-Testing Workers*, WASH. POST, Apr. 19, 2001, at E1, available at <http://www.washingtonpost.com/ac2/wp-dyn/A34877-2001Apr18?language=printer>.

²⁶ Tamar Lewin, *Commission Sues Railroad To End Genetic Testing In Work Injury Cases*, N.Y. TIMES, Feb. 10, 2001, <http://query.nytimes.com/gst/fullpage.html?res=9F01E6DC1331F933A25751CoA9679C8B63&sec=&spon=&pagewanted=all>.

²⁷ *Id.*

knowledge, to DNA analysis.²⁸ Burlington Northern alleged that it undertook the testing as an attempt to comply with workplace OSHA regulations.²⁹ Burlington chose to settle without admitting any wrongdoing rather than face prolonged litigation.³⁰ The EEOC's case against Burlington Northern was the first case in the United States brought by employees against an employer alleging workplace genetic discrimination.³¹ This case marked the beginning of a battle between employees and employers over medical privacy.

D. CONSEQUENCES OF GENETIC DISCRIMINATION

The fear of losing a job or being denied insurance coverage causes some individuals to avoid genetic testing and, consequently, prevents those individuals from enjoying the potential benefits of early detection or prevention of disease.³² Genetic tests only reveal an individual's *predisposition* to a certain disease or condition, they do not predict with complete certainty whether the disease or condition will actually develop.³³ Therefore, to rely on genetic testing for employment decisions or health insurance coverage rights is especially pernicious; although, health insurers and employers may still use genetic information as a way of screening out "at-risk" individuals because it is often financially beneficial to the insurer or employer.

Because of fear of this potential discrimination, some individuals may withhold their genetic information, even from their health care providers. This can lead to new problems. First, individuals may put themselves in a higher level of health risk by hiding genetic information or refusing to take genetic tests³⁴ because they lose the

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² Louise M. Slaughter, *The Genetic Info. Nondiscrimination Act: Why Your Personal Genetics are Still Vulnerable to Discrimination*, 88 SURGICAL CLINICS OF NORTH AMERICA 723, 724–725 (2008).

³³ Clayton, *supra* note 23, at 563.

³⁴ See Kira A. Apse et al., *Perceptions of Genetic Discrimination Among At-Risk Relatives of Colorectal Cancer Patients*, 6 GENETICS IN MED. 510, 510–16 (2004).

benefit of having a more complete medical diagnosis that could enable their health providers to better treat or prevent diseases or disorders.

Second, failure to release genetic information can have adverse financial consequences on the individual. Early detection of an illness can lessen the financial burden on patients, their families, and society as a whole by allowing doctors to prescribe less-costly preventative treatments (where possible) instead of expensive remedial treatment options. Thus, individuals who avoid genetic testing or refuse to disclose the results of these tests may face thousands of dollars in additional health care costs if a preventative illness later manifests. Medical debt is a leading source of personal financial bankruptcy in the United States, and it can lead to home foreclosures and financial ruin for an entire family.³⁵

Genetic discrimination does not only affect the individual facing discrimination, but it also affects his or her entire family. For instance, some genetic illnesses are hereditary in nature and early detection of such illnesses can prompt those affected to take necessary precautions for the entire family. In addition, an individual's medical information can impact the ability of his family members to access insurance or employment. If, for example, genetic testing reveals that a father has a certain hereditary disease, and his insurance company becomes aware of these test results, the insurance company may refuse to insure (or raise the rates of coverage) both the father and his children because the children may have inherited their father's predisposition to disease.

In addition, genetic discrimination can have a negative impact on the American health care system as a whole. Genetic testing can lessen the negative effects of many illnesses through prevention and individually designed therapeutic treatments.³⁶ However, if individuals refuse to undergo genetic testing out of fear of discrimination, the health care system will be faced with an increased financial and physical burden on resources, and health care costs will rise across the board.

Finally, fear of genetic discrimination hinders important genetic research. Genetics are used in clinical research to identify genetic

³⁵ Josh Fischman, *Medical Bills Lead To Personal Bankruptcy*, U.S. NEWS & WORLD REPORT, Feb. 2, 2005, <http://health.usnews.com/usnews/health/briefs/publichealth/hbo50202c.htm>.

³⁶ Nat'l Human Genome Research Inst., Genetics, Disease Prevention and Treatment, <http://www.genome.gov/19016938> (last visited Feb. 19, 2009).

contributors to and identifiers of diseases.³⁷ However, many people refuse to participate in clinical studies because they fear having their genetic information used against them by insurers and employers.³⁸ For example, people at risk for hereditary colon cancer who were offered genetic testing as part of a research study stated that their primary concern about testing was fear of genetic discrimination.³⁹ Thus, researchers lose valuable resources that may, in the long-term, help to create more efficient, cost-effective genetic tests and, most importantly, could lead to cures for numerous diseases or conditions.

III. STATE GENETIC PRIVACY REGULATION

Forty-two states have legislation providing some protection against genetic discrimination in health insurance.⁴⁰ Five additional states and the District of Columbia provide more limited protection against genetic discrimination in health insurance.⁴¹ Thirty-four states have laws providing some protection against individual genetic discrimination in employment.⁴² Many state genetic anti-discrimination laws also include specific provisions relating to genetic privacy, with nineteen states establishing specific penalties for violating genetic privacy laws.⁴³ Only three states have no legislation

³⁷ GENETICS & PUB. POLICY CTR., U.S. PUBLIC OPINION ON USES OF GENETIC INFORMATION AND GENETIC DISCRIMINATION (2007), http://www.dnapolicy.org/resources/GINAPublic_Opinion_Genetic_Information_Discrimination.pdf.

³⁸ *Id.*

³⁹ Donald W. Hadley et al., *Genetic Counseling and Testing in Families with Hereditary Nonpolyposis Colorectal Cancer*, 163 ARCHIVES OF INTERNAL MED. 573, 573–82 (2003).

⁴⁰ Nat'l Conf. of State Legislatures, State Genetic Nondiscrimination in Health Insurance Laws, <http://www.ncsl.org/programs/health/genetics/ndishlth.htm> (last visited Feb. 19, 2009).

⁴¹ *Id.*

⁴² Nat'l Conf. of State Legislatures, State Genetics Employment Laws [hereinafter State Genetics Employment Laws], <http://www.ncsl.org/programs/health/genetics/ndiscrim.htm> (last visited Feb. 19, 2009).

⁴³ Nat'l Conf. of State Legislatures, State Genetic Privacy Laws, <http://www.ncsl.org/programs/health/genetics/prt.htm> (last visited Feb. 19, 2009).

regarding the privacy of genetic information or genetic discrimination.⁴⁴

Although most states have some form of statute banning the use of genetic information in the workplace, the scope of these laws varies widely. All laws prohibit employment discrimination based on the results of genetic testing, but only a few extend the protections to inherited characteristics, family member results, family history, and information about the receipt of genetic services.⁴⁵ Most states also restrict employer access to genetic information, as well as restricting employers from performing or administering genetic tests.⁴⁶ Some states make exceptions to statutory requirements if genetic information identifies individuals who may be a safety risk in the workplace.⁴⁷

GINA does not displace any federal or state statute that provides protection equal to or greater than GINA. However, for the three states that have no such legislation regarding genetic information privacy or genetic discrimination, the new federal law will create a minimum regulation.

IV. FEDERAL GENETIC PRIVACY REGULATION PRIOR TO GINA

A. THE AMERICANS WITH DISABILITIES ACT OF 1990

The ADA prohibits discrimination in any aspect of employment on the basis of a disability, unless the disability prohibits adequate job performance for employers with fifteen or more employees.⁴⁸ The original language of the ADA does not specifically refer to genetic information; however, in 1995, the EEOC stated that the "ADA prohibits discrimination against workers based on their genetic makeup."⁴⁹ Despite the EEOC's interpretation of the ADA, the EEOC

⁴⁴ *Id.*

⁴⁵ State Genetics Employment Laws, *supra* note 42.

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ Americans with Disabilities Act of 1990, *supra* note 1.

⁴⁹ *Analyzing Genetic Discrimination in the Workplace*, HUMAN GENOME NEWS, Feb. 2002, at 9–11, available at http://www.ornl.gov/sci/techresources/Human_Genome/publicat/hgn/v12n1/HGN121_2.pdf.

supports enacting stand-alone legislation protecting genetic privacy because the ADA does not explicitly address genetic discrimination.⁵⁰ In addition, the ADA may be limited in its application and may not protect employees from all types of genetic discrimination. As EEOC Commissioner Paul Miller noted,

[F]or example, ADA does not protect workers from requirements or requests to provide genetic information to their employers. . . . In addition, once the applicant is hired, the employer may request that the employee take a medical exam, such as a genetic test, if the employer can demonstrate that the information from that test is job related and consistent with business necessity.⁵¹

Although the EEOC adopted a view that favors inclusion of genetic information protection within the meaning of the ADA, it lacks the force of explicit genetic anti-discrimination law. In addition, genetic discrimination differs greatly from traditional disabilities discrimination and the ADA does not provide sufficient protection. Therefore, courts may find that the ADA does not cover genetic-predisposition discrimination. Thus, GINA is necessary to provide full protection.

B. THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996

The Health Insurance Portability and Accountability Act of 1996⁵² (“HIPAA”) has been viewed as an “important step[] toward banning genetic discrimination in health insurance,” yet, it has also been criticized for being insufficient in banning all discrimination.⁵³ HIPAA explicitly indicates that genetic information, including family

⁵⁰ LANMAN, *supra* note 7, at ii–iii.

⁵¹ *Hearing on Genetic Information in the Workplace*, *supra* note 16.

⁵² Health Insurance Portability and Accountability Act of 1996, *supra* note 1.

⁵³ *Technological Advances in Genetic Testing: Implications for the Future: Hearing on H.R. 2748 Before the H. Comm. on Science & Technology*, 104th Congress (1996) (statement of Rep. Louise Slaughter) [hereinafter *Technological Advances in Genetic Testing*].

history and the results of genetic testing, cannot be used as a pre-existing condition.⁵⁴ A pre-existing condition is “one for which medical advice, diagnosis, care, or treatment was recommended or received during the six-month period prior to an individual’s enrollment date.”⁵⁵ By excluding pre-existing conditions under HIPAA, a new employer’s health insurance plan must give credit for the length of time the employee had prior continuous health coverage.⁵⁶ HIPAA also prohibits a group health plan or an issuer of a group health plan from denying continuation or renewal of coverage based on genetic information, and it prohibits the use of genetic information to determine eligibility, to set premiums, or to charge individuals within a group different premiums.⁵⁷

However, HIPAA only applies to employer-based and commercially issued group health insurance, such that HIPAA protection applies to individuals within the group plans, and it does not prohibit the use of genetic information as a basis for charging a whole group a higher rate for health insurance.⁵⁸ In addition, HIPAA does not prohibit group health plans or insurers from requiring or requesting genetic testing.⁵⁹ Under HIPAA, neither insurers nor group health plans must get authorization before disclosing genetic information; however, HIPAA allows insurers and group health plans to exclude all coverage for a particular condition or to impose lifetime caps on all benefits or on specific benefits.⁶⁰ Finally, HIPAA only protects genetic privacy in certain contexts related to health insurance and does not protect genetic privacy within employment settings.⁶¹

⁵⁴ *Id.*

⁵⁵ Fact Sheet, The Health Insurance Portability and Accountability Act, <http://www.dol.gov/ebsa/newsroom/fshipaa.html> (last visited Feb. 19, 2009).

⁵⁶ *Id.*

⁵⁷ *Technological Advances in Genetic Testing*, *supra* note 53.

⁵⁸ *Id.*

⁵⁹ NANCY L. JONES & AMANDA SARATA, GENETIC INFORMATION: LEGAL ISSUES RELATING TO DISCRIMINATION AND PRIVACY 7–8 (2008), http://biotech.law.lsu.edu/crs/RL30006_20080310.pdf.

⁶⁰ *Id.* at 7.

⁶¹ *Id.* at 8.

C. TITLE VII OF CIVIL RIGHTS ACT

Title VII of the Civil Rights Act prevents employers from discriminating on the basis of race, sex, national origin, nationality, or religion.⁶² Treatment that causes a “disparate impact” on an employee can be a basis for violating Title VII.⁶³ Disparate treatment occurs when an employer treats a member of a protected class differently from others who are not members of the protected class.⁶⁴ Because some genetic markers are specifically associated with protected groups, such as sickle cell anemia in African Americans, an employee may argue genetic discrimination under Title VII. However, this is not a forceful argument on behalf of the employee. The employer can often successfully rebut an employee’s claim by arguing that it is discriminating based on genetic markers (which is not prohibited under Title VII) and not on the groups that carry them. In the example above, the plaintiff-employee must show that the genetic testing, while not intentionally aimed at a protected class, nonetheless has a disparate impact of discriminating against that protected class, a difficult burden to overcome.⁶⁵

D. FOURTH AMENDMENT TO THE U.S. CONSTITUTION

The Fourth Amendment to the U.S. Constitution states that “the right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated.”⁶⁶ The Supreme Court has interpreted the Fourth Amendment to include a right of privacy for medical information.⁶⁷ In *Norman-Bloodsaw v. Lawrence Berkeley Lab*, the Ninth Circuit Court of Appeals held that the privacy of genetic information is

⁶² 42 U.S.C. § 2000e-2(a) (2000).

⁶³ *Id.* at § 2000e-2(k).

⁶⁴ *Id.*

⁶⁵ Genetic Information Nondiscrimination Act of 2007, S. REP. NO. 110-048, at 11 (2007), available at http://thomas.loc.gov/cgi-bin/cpquery/?&sid=cp110dULmR&refer=&r_n=sro48.110&db_id=110&item=&sel=TOC_33535&.

⁶⁶ U.S. CONST. amend. IV.

⁶⁷ *Whalen v. Roe*, 429 U.S. 589, 598–605 (1965).

protected under the Fourth Amendment's prohibition of illegal searches and seizures and is also protected under the Fifth and Fourteenth Amendments' Due Process Clauses.⁶⁸ The *Norman-Bloodsaw* Court held that a person has a legitimate expectation of privacy over a bodily fluid sample, from which most DNA is collected.⁶⁹

V. THE GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008

A. FROM THE COMPLETION OF THE HUMAN GENOME PROJECT TO THE PASSAGE OF GINA

Since 1990, the state and federal governments have made progress in attempting to create a fair and comprehensive law to protect the genetic privacy of individuals who undergo genetic testing. In 1995, Representative Slaughter and Representative Stearns⁷⁰ introduced the first pieces of legislation relating directly to genetic discrimination in health insurance. In 1996, Senator Snowe introduced similar legislation in the Senate.⁷¹ None of these bills passed in the 104th Congress.⁷² Similar legislation was introduced in the 105th and 106th Congresses and was rejected.⁷³ In 2002, Senator Snowe introduced an early version of what would eventually become GINA that addressed discrimination in both health insurance and employment decisions, but the bill was once again rejected.⁷⁴ Yet again, similar legislation was introduced in the 108th Congress, and like its predecessors, it too failed.⁷⁵

⁶⁸ *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260, 1268–69 (9th Cir. 1998).

⁶⁹ *Id.* at 1270.

⁷⁰ H.R. 2748, 104th Cong. (1995); H.R. 2690, 104th Cong. (1995).

⁷¹ S. 1694, 104th Cong. (1996).

⁷² Genetic Nondiscrimination Federal Legislation Archive, <http://www.genome.gov/11510239> (last visited Feb. 19, 2009).

⁷³ *See, e.g.*, S. 89, 105th Cong. (1997); S. 1322, 106th Cong. (1999).

⁷⁴ S. 1995, 107th Cong. (2002).

⁷⁵ *See, e.g.*, S. 1053, 108th Cong. (2003).

Then, in 2007, GINA was introduced in the House of Representatives.⁷⁶ On April 25, 2007, GINA passed in the House by a vote of 420–3.⁷⁷ On April 24, 2008, the Senate took up GINA, and passed the amended measure by a vote of 95–0. On May 1, 2008, the House passed the Senate version of GINA by a vote of 414–1, and finally, President Bush signed H.R. 493, the Genetic Information Nondiscrimination Act of 2008 into law on May 21, 2008.⁷⁸

B. UNDERSTANDING GINA OF 2008

GINA is a comprehensive bill that provides significant protections against genetic discrimination by health insurers and employers. In general, GINA bars group health plans and health insurers from cancelling, denying, and refusing to renew or changing the terms of coverage based solely on genetic information.⁷⁹ GINA also prohibits employers from hiring, firing, placing, or making promotional decisions based solely on an individual's genetic information.⁸⁰

Title I: Genetic Nondiscrimination in Health Insurance

Title I of GINA, applying to health insurance issuers, strengthens and clarifies HIPAA through amendments to the relevant existing statutes: the Employee Retirement Income Security Act of 1974 (“ERISA”), the Public Health Services Act (“PHSA”), the Internal Revenue Code (“IRC”), and the Social Security Act (“SSA”).⁸¹ In effect, group health care plans under ERISA, non-federal governmental and individual health care plans under the PHSA, church health care plans

⁷⁶ H.R. 493, 110th Cong. (2007).

⁷⁷ Press Release, Coalition for Genetic Fairness, Coalition for Genetic Fairness Applauds U.S. House of Rep. for Passing Genetic Info. Nondiscrimination Act (Apr. 25, 2007), available at http://www.geneticalliance.org/ksc_assets/publicpolicy/pressreleasepassedhouse04_25_07.pdf.

⁷⁸ Nat'l Human Genome Research Inst., Genetic Information Nondiscrimination Act of 2007–2008, <http://www.genome.gov/24519851> (last visited Feb. 19, 2009).

⁷⁹ Genetic Info. Nondiscrimination Act of 2008, *supra* note 9, at §§ 101–105.

⁸⁰ *Id.* at §§ 201–205.

⁸¹ *Id.* at §§ 101–103.

under the IRC, and Medigap health care plans under the SSA are under the jurisdiction of GINA.⁸²

In summary, Title I limits health insurers from using genetic information in such a way that may lead to discrimination. For individuals who have undergone genetic testing and have genetic information on file, health insurers cannot require individuals to provide their genetic information or genetic information of a family member for the purpose of determining their eligibility, coverage, underwriting, or premium-setting decisions.⁸³ In addition, health insurers cannot use “genetic information either collected with intent, or incidentally, to make enrollment or coverage decisions.”⁸⁴ For individuals who have not yet undergone genetic testing, health insurers cannot require them or their family members to submit to genetic testing.⁸⁵ Lastly, Title I prohibits genetic information from being used as a pre-existing condition in the Medicare supplemental policy and individual health insurance markets.⁸⁶

However, in cases where health insurers and external research institutions collaborate for research purposes, health insurers may request that an individual undergo a genetic test.⁸⁷ The individual’s voluntary decision to undergo such genetic testing does not influence the premium or enrollment status of the individual.⁸⁸ Also, an insurer can require genetic information to make coverage determinations for a specific claim. For instance, “the insurer may request information about an individual’s BRCA [breast cancer] status to determine

⁸² *Id.*

⁸³ COALITION FOR GENETIC FAIRNESS, WHAT DOES GINA MEAN?: A GUIDE TO THE GENETIC INFORMATION NONDISCRIMINATION ACT 7, <http://www.geneticfairness.org/ginapublication.pdf> (last visited Feb. 19, 2009).

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ *Id.* A preexisting condition is a medical condition that existed before an individual obtains health insurance. Because a person with a preexisting condition can be costly to an insurance company, it is in the insurance company’s best interest to exclude individuals who have preexisting conditions. Thus, an insurance company may limit or exclude coverage for certain preexisting conditions. Insurance Information Institute, Preexisting Condition, <http://www.iii.org/individuals/health/terms/condition/> (last visited Feb. 19, 2009).

⁸⁷ *Id.*

⁸⁸ *Id.*

coverage for prophylactic mastectomy.”⁸⁹ Yet, the insurer may not ask more than the minimum information necessary for decisionmaking.⁹⁰

In addition, GINA provides for an enforcement mechanism of the above provisions.⁹¹ GINA also directs the Secretary of Health and Human Services to revise the HIPAA Privacy Rule to show that genetic information is to be treated as health information.⁹² The Title I health insurance provisions are limited in their applicability; the provisions do not extend to:

Members of the US military, veterans obtaining healthcare through the Veteran’s Administration, or the Indian Health Service; genetic discrimination in life, disability, or long-term-care insurance; genetic services, the practice of medicine, or the authority of healthcare professionals. . . request[ing] genetic test[ing] for the purpose[s] of that individual’s medical benefit; or individual’s manifested disease or condition.⁹³

Title II: Genetic Nondiscrimination in Employment

Title II of GINA, which takes effect November 21, 2009, regulates employers, employment agencies, labor organizations, and training programs controlled by joint labor-management committees.⁹⁴ GINA’s definitions of “employee” and “employer” are exactly the same as the definitions under Title VII of the Civil Rights Act.⁹⁵

⁸⁹ *Id.* BRCA is a gene involved in cases of hereditary breast and ovarian cancer. “A woman’s lifetime chance of developing breast cancer is greatly increased if she inherits an altered BRCA gene.” Nat’l Cancer Inst., Genetic Testing for BRCA1 and BRCA2: It’s Your Choice, <http://www.cancer.gov/cancertopics/factsheet/risk/brca> (last visited Feb. 19, 2009).

⁹⁰ COALITION FOR GENETIC FAIRNESS, *supra* note 83.

⁹¹ Genetic Info. Nondiscrimination Act of 2008, *supra* note 9, at §§ 101–106.

⁹² *Id.* at § 105(a).

⁹³ *Id.* at 8.

⁹⁴ *Id.* at §§ 201–205.

⁹⁵ *Id.* at § 201(2) (with 42 U.S.C. § 2000e(f) providing the definition of “employees” and § 2000e(b) providing the definition of “employers”).

Under GINA, genetic information must be kept as part of the employee confidential medical record.⁹⁶ In summary, Title II puts limitation on employers from using genetic information that may lead to discrimination. For one, an employer is prohibited from using genetic information as a factor in making decisions regarding “hiring, promotion, terms or conditions, privileges of employment, compensation, or termination.”⁹⁷ In addition, an employer, employment agency, labor organization, or training program may not limit, segregate or classify an employee or member, or deprive that employee or member of employee opportunities, on the basis of genetic information.⁹⁸ Title II prevents an employer, employment agency, labor organization, or training program from “requesting, requiring, or purchasing genetic information of the individual or a family member of the individual except in rare cases.”⁹⁹ For instance, Title II does allow these employment-related organizations to obtain genetic information when it is in compliance with family and medical leave laws; when it is necessary to monitor biological effects of toxic substances in the workplace; and when it is necessary for DNA analysis for law enforcement purposes at a forensic laboratory.¹⁰⁰

Title II also prohibits employment agencies, labor organizations, and training programs from refusing to refer an individual for employment based on genetic information, or from causing an employer to discriminate against an individual on the basis of genetic information.¹⁰¹ An employer, labor organization, or joint labor-management committee is prohibited from using genetic information in deciding “admission to or employment in any program for apprenticeship or training and retraining, including on-the-job training.”¹⁰² Lastly, a labor organization cannot exclude or expel from membership because of genetic information.¹⁰³

⁹⁶ Genetic Info. Nondiscrimination Act of 2008, *supra* note 9, at § 206.

⁹⁷ COALITION FOR GENETIC FAIRNESS, *supra* note 83, at 9.

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

Title II requires an individual's genetic information to be kept in a confidential medical file except in certain cases.¹⁰⁴ This information may be disclosed when it is inadvertently provided as part of the individual's medical history or the medical history of a family member.¹⁰⁵ Also, when the information is publicly available, the employers are relieved from keeping the information confidential.¹⁰⁶ This normally confidential information may also be disclosed as part of an employer-sponsored genetic monitoring program or if state or federal law requires the genetic monitoring program as long as the individual gives his or her written consent.¹⁰⁷ However, genetic information may only be partially disclosed for such monitoring programs: only the healthcare professional and the employee can know the identity of the individual and his or her related identifiable genetic information, and the employee must be informed of individual monitoring results. Therefore, the employer can only have access to the collective genetic information of the entire group of employees, without identifying information.¹⁰⁸ With the individual's written authorization, Title II allows genetic information to be disclosed for use in health or genetic services, including services offered as part of a wellness program offered by the employer.¹⁰⁹ Lastly, if the employer operates as a law enforcement entity, then genetic information may be disclosed.¹¹⁰

GINA clarifies that a "disparate impact" does not create a cause of action under its provisions.¹¹¹ However, GINA requires that a commission be established six years after the date of its enactment to review the science of genetics and to make recommendations to Congress regarding whether to add to GINA a "disparate impact" cause of action similar to that of Title VII.¹¹²

¹⁰⁴ Genetic Info. Nondiscrimination Act of 2008, *supra* note 9, at § 206.

¹⁰⁵ COALITION FOR GENETIC FAIRNESS, *supra* note 83, at 15–16.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ Genetic Info. Nondiscrimination Act of 2008, *supra* note 9, at § 208.

¹¹² *Id.* at § 208(b).

C. THE IMPLICATIONS, REGULATION, AND ENFORCEMENT OF GINA

Title I of GINA will begin affecting health insurance policies for plan years after May 21, 2009.¹¹³ The three agencies responsible for enforcement of Title I are the U.S. Departments of Labor (“DOL”), U.S. Department of Health and Human Services (“HHS”), and the U.S. Treasury Department.¹¹⁴ These three agencies must issue final regulations within one year of GINA’s enactment.¹¹⁵ GINA also requires that certain amendments to the HIPAA Privacy Rule be issued within sixty days of enactment.¹¹⁶ GINA provides that Title I should be construed to allow use of information about a manifested disease or disorder by health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies to establish premiums or conditions of eligibility.¹¹⁷ However, only the minimum amount of information required to achieve this purpose may be requested.¹¹⁸

The remedies provided by GINA are imposed by the HHS Secretary, and consist mostly of monetary damages. Generally, Title II applies the remedies and enforcement mechanisms available in Title VII of the Civil Rights Act.¹¹⁹ The EEOC is responsible for the enforcement of Title II, and it is required to issue final regulations within one year of enactment.¹²⁰

GINA provides a “firewall” between Title I and Title II such “that employers are not liable for health insurance violations under civil rights laws unless the employer has separately violated a provision of Title II governing employers.”¹²¹ Section 209 of GINA provides that nothing in Title II will be construed to limit the rights or protections

¹¹³ *Id.* at § 213.

¹¹⁴ *Id.* at § 106.

¹¹⁵ *Id.* at §§ 105(b), 106.

¹¹⁶ *Id.* at § 105(c).

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.* at § 207(a) (applying 42 U.S.C. § 2000e-4, et seq.).

¹²⁰ *Id.* at § 211.

¹²¹ 154 CONG. REC. H2972 (daily ed. May 1, 2008) (statement of Rep. Dingell).

of an individual under any federal or state statute that provides equal or greater protection.¹²² In addition, nothing in Title II will limit the rights or protections of an individual to bring action or enforce penalties for any violation under Title I of GINA, certain sections of ERISA, PHSA, and IRC.¹²³

The passage of GINA is just the first step in protecting the public from misuse of genetic information by health insurers and employers. In addition, GINA will benefit the field of clinical research and health care delivery by improving patients' participation in research studies that involve collection of genetic information.¹²⁴

VI. CONCLUSION

With the advancements in biotechnology that have allowed scientists to understand and access genetic information, genetic discrimination has become a serious issue, not only to individuals with genetic predisposition to disease, but to their families, their communities, and to scientific communities. Congress determined that state laws, federal health insurance, employment and other antidiscrimination laws failed to effectively protect the public from genetic discrimination. In response, Congress passed the Genetic Information Nondiscrimination Act of 2008. GINA provides the first step in creating a comprehensive measure to prevent genetic discrimination in employment and insurance practices.

However, challenges still remain. The federal agencies must write the implementing regulations that will provide detailed guidance for health insurers and employers about how to comply with the new law. The Departments of Labor, Health and Human Services, and Treasury welcomed comments from the public before writing such regulations.¹²⁵ Public comments are one method of making certain to write an implementing regulation that will maximize the benefits of

¹²² Genetic Info. Nondiscrimination Act of 2008, *supra* note 9, at § 209.

¹²³ *Id.*

¹²⁴ Genetic Info. Nondiscrimination Act of 2007, S. 358, 110th Cong. (2007). The Senate report accompanying the bill provided that, "[e]stablishing these protections will allay concerns about the potential for discrimination and encourage individuals to participate in genetic research and to take advantage of genetic testing, new technologies, and new therapies." See S. Rep. No. 110-48, at 1 (2007).

¹²⁵ Request for Info. Regarding Sections 101 through 104 of the Genetic Info. Nondiscrimination Act of 2008, 73 Fed. Reg. 60,208 (Oct. 10, 2008).

GINA. The regulations need to clearly inform health care professionals and patients. Also, the genetic tests need to be “safe, reliable, and marketed in a clear and truthful manner.”¹²⁶ Advisory groups recognize the need for regulatory reform to improve the analytic and clinical validity of genetic tests.¹²⁷ In addition, GINA does not address genetic discrimination in life insurance, disability insurance, or long-term-care insurance.¹²⁸

The actual effect of GINA will remain unclear until the regulating agencies present a detailed regulatory scheme and the law goes into effect. In adopting the new regulatory scheme, the regulating agencies will need to strike a delicate balance between the public interest and individual privacy.

¹²⁶ Kathy L. Hudson et al., *Keeping Pace with the Times—The Genetic Information Nondiscrimination Act of 2008*, 358 NEW ENG. J. MED. 2661, 2663 (2008), available at <http://content.nejm.org/cgi/content/full/358/25/2661>.

¹²⁷ *Id.*

¹²⁸ Nat'l Human Genome Research Inst., Genetic Discrimination Fact Sheet, <http://www.genome.gov/10002328> (last visited Feb. 19, 2009).